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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,408	12/26/2001	Larry Caldwell	CALD-005	3760

24353 7590 07/17/2007

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER
OH, SIMON J

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/029,408	CALDWELL ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's response, affidavit under 37 C.F.R. 1.132, and submitted references, all received on 09 May 2007.

Withdrawal of Finality

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-18 and 24-33 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards and Biedermann *et al.* is hereby withdrawn.

The rejection of Claims 19-23 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards, Biedermann *et al.*, and Shudo *et al.* is hereby withdrawn.

The rejection of Claims 1-18 and 24-33 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards is hereby withdrawn

Claims 1-3, 5-8, 10-12, 14-18, 29 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559).

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards

patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

The examiner finds no novelty claim limitations dealing with the specific placement of NSAID formulations on a subject and shifts the burden onto the applicant to demonstrate how the instantly claimed invention shows unexpected results from what is known in the prior art. It is the position of the examiner that topical forms disclosed in the prior art such as films sufficiently read on the instantly claimed invention so as to make the use of patches in treatment obvious to one of ordinary skill in the art. Thus, the instantly claimed invention is *prima facie* obvious.

Claims 4, 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Hirano *et al.* (U.S. Patent No. 5,869,087)

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an

occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel, nor does it disclose the topical formulation in the form of a patch

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Hirano *et al.* patent is used here to show that it is known in the art that anti-inflammatory drugs such as diclofenac, indomethacin, ibuprofen and ketoprofen may be formulated into a patch, to be included in amounts ranging from 0.1% to 10% by weight (See Column 3, Line 65 to Column 4, Line 19; and Claims 1 and 10).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

One of ordinary skill in the art would be motivated to combine the Bockow patent with the Hirano *et al.* patent in order to treat pain using a topical formulation in the form of a patch,

for the reason that a patch may be considered less messy than the use of a cream or gel. As the Bockow and the Hirano *et al.* patents both deal with topical compositions containing commonly known anti-inflammatory substances, they are considered to be analogous, and therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together.

The examiner finds no novelty claim limitations dealing with the specific placement of NSAID formulations on a subject and shifts the burden onto the applicant to demonstrate how the instantly claimed invention shows unexpected results from what is known in the prior art. It is the position of the examiner that topical forms disclosed in the prior art such as films sufficiently read on the instantly claimed invention so as to make the use of patches in treatment obvious to one of ordinary skill in the art. Thus, the instantly claimed invention is *prima facie* obvious.

Claims 19-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Shudo *et al.* (U.S. Patent Application Publication No. 2002/0176886)

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans

(See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel. The Bockow patent does not provide for kits containing a topical formulation and instructions for use according to a claimed method of treatment.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Shudo *et al.* reference discloses kits comprising topical patch formulations as well as instructions for use, which may be printed or embodied in the form of electronic media (See Section 0044).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

One of ordinary skill in the art would have been motivated to combine the Shudo *et al.* with the aforementioned references, in order to provide topical dosage forms in a kit that further comprises instructions for use in accordance with the treatment of conditions such as carpal tunnel syndrome. As the prior art references disclose the use of topical formulations, they are considered to be analogous such that one of ordinary skill in the art would have a reasonable expectation of success in combining the references together. Thus, the instantly claimed invention is *prima facie* obvious.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559), Hirano *et al.* (U.S. Patent No. 5,869,087) and Shudo *et al.* (U.S. Patent Application Publication No. 2002/0176886)

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel, nor

does it disclose the topical formulation in the form of a patch. The Bockow patent does not provide for kits containing a topical formulation and instructions for use according to a claimed method of treatment.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Hirano *et al.* patent is used here to show that it is known in the art that anti-inflammatory drugs such as diclofenac, indomethacin, ibuprofen and ketoprofen may be formulated into a patch, to be included in amounts ranging from 0.1% to 10% by weight (See Column 3, Line 65 to Column 4, Line 19; and Claims 1 and 10).

The Shudo *et al.* reference discloses kits comprising topical patch formulations as well as instructions for use, which may be printed or embodied in the form of electronic media (See Section 0044).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

One of ordinary skill in the art would have been motivated to combine the Shudo *et al.* with the aforementioned references, in order to provide topical dosage forms in a kit that further comprises instructions for use in accordance with the treatment of conditions such as carpal tunnel syndrome. As the prior art references disclose the use of topical formulations, they are considered to be analogous such that one of ordinary skill in the art would have a reasonable expectation of success in combining the references together. Thus, the instantly claimed invention is *prima facie* obvious.

One of ordinary skill in the art would be motivated to combine the Bockow patent with the Hirano *et al.* patent in order to treat pain using a topical formulation in the form of a patch, for the reason that a patch may be considered less messy than the use of a cream or gel. As the Bockow and the Hirano *et al.* patents both deal with topical compositions containing commonly known anti-inflammatory substances, they are considered to be analogous, and therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together.

One of ordinary skill in the art would have been motivated to combine the Shudo *et al.* with the aforementioned references, in order to provide topical dosage forms in a kit that further comprises instructions for use in accordance with the treatment of conditions such as carpal tunnel syndrome. As the prior art references disclose the use of topical formulations, they are considered to be analogous such that one of ordinary skill in the art would have a reasonable expectation of success in combining the references together. Thus, the instantly claimed invention is *prima facie* obvious.

Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559), Hirano *et al.* (U.S. Patent No. 5,869,087), and a bandage.

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel, nor does it disclose the topical formulation in the form of a patch

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Hirano *et al.* patent is used here to show that it is known in the art that anti-inflammatory drugs such as diclofenac, indomethacin, ibuprofen and ketoprofen may be formulated into a patch, to be included in amounts ranging from 0.1% to 10% by weight (See Column 3, Line 65 to Column 4, Line 19; and Claims 1 and 10).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

One of ordinary skill in the art would be motivated to combine the Bockow patent with the Hirano *et al.* patent in order to treat pain using a topical formulation in the form of a patch, for the reason that a patch may be considered less messy than the use of a cream or gel. As the Bockow and the Hirano *et al.* patents both deal with topical compositions containing commonly known anti-inflammatory substances, they are considered to be analogous, and therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together.

One of ordinary skill in the art would find it advantageous to use a patch containing an anti-inflammatory drug in conjunction with a bandage. Bandages are well known for holding dressings and other topical formulations in place so as to avoid the loss of contact between the formulation between such a therapeutic composition and the affected area. Bandages are also useful in restricting the movement of a joint afflicted with pain so that the decrease in movement also decreases the chance of a sharp jerk or movement in the joint that may trigger additional pain. In either application, a bandage applied to a subject suffering from carpal tunnel syndrome

would constitute a "wrist strap" in the broad sense of the term, without any further or more specific definition by the instant disclosure. Thus, the instantly claimed invention is *prima facie* obvious.

Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bockow (U.S. Patent No. 5,709,855) in view of Edwards (U.S. Patent No. 5,989,559) and Liebschutz (PCT Publication WO 02/22109 A2).

The Bockow patent teaches topical compositions for treating inflammation and/or pain (See Abstract). The compositions may contain a cyclooxygenase inhibitor such as diclofenac, indomethacin, ibuprofen and ketoprofen, in amounts ranging from 3% to 25% by weight (See Column 5, Lines 23-43; and Column 6, Lines 40-42). The disclosed composition may be in various common forms of topical compositions such as gels and creams (See Column 6, Lines 4-15). The compositions are intended for application to warm-blooded animals including humans (See Column 3, Lines 6-15). The compositions may be applied from 1 to 4 times daily, and an occlusive bandage may be applied after the application of the composition for a period of 4 to 10 hours (See Column 7, Lines 15-24).

The Bockow patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel, nor does it disclose the use of diclofenac epolamine in an amount of 1.3% by weight in the form of a patch.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

The Liebschutz *et al.* reference discloses a patch containing diclofenac (See Abstract). The diclofenac may be present in the form of diclofenac epolamine in an amount that is preferably from 1% to 5% of the matrix layer (See Page 3, Section (b)(1)).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Bockow and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow.

It would be obvious to one of ordinary skill in the art to combine the Bockow patent with the Liebschutz *et al.* reference, as one would be motivated to use the patch disclosed in Liebschutz *et al.* for its disclosed advantages of good adhesion without irritation and improved bioavailability (See Page 2, first paragraph). As the Bockow and Liebschutz *et al.* reference are both drawn to topical formulations of anti-inflammatory drugs such as diclofenac for the treatment of pain, the references are analogous and therefore, one of ordinary skill in the art would have a reasonable expectation of success in combining the references together. Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments with respect to Claims 1-34 have been considered but are moot in view of the new grounds of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER